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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,620	AU ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,26-28,30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,26-28,30 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 10/15/2008, are acknowledged and entered. Claim 31 has been cancelled by Applicant. Claims 22, 26-28, 30, and 32-34 are pending and under examination.

Response to Arguments

Any previous rejections and/or objections to claim 31 are withdrawn as being moot in light of Applicant's cancellation of the claim.

Applicant's arguments with respect to claims 22, 26-28, 30, and 32-34 have been considered but are moot in view of the new ground(s) of rejection. The Examiner notes that Applicant states that claims 22, 26-28, 30, and 32-34 were rejected under 35 U.S.C. 103 as obvious over DuPont in view of the Pre-Brief Conference held 7/10/2008. However, at page 5 of the previous Office Action the Examiner indicated that this rejection is **withdrawn** in light of the Pre-Brief Conference held 7/10/2008.

Claim Objections

Claim 22 is objected to because of the following informalities: claim 22 contains a typo (the slash "/" after (c) in line 10). Appropriate correction is required.

Claim Rejections - 35 USC § 112 – New Ground of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 26-28, 30, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites the limitation "...the required dose of suramin can be determined in step (b)..." in line 19. There is insufficient antecedent basis for this limitation in the claim. In the instant case, line 19 of claim 22 recites that the required dose of

suramin can be determined in step (b) by the steps (b1)-(b3). However, step (b) of claim 22 has been amended to recite cytotoxic agents and no longer recites the limitation "required dose" of suramin referred to line 19 of the claims.

Claims 22, 26-28, 30, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 22 recites a kit that contains "radiation" (see last line of part (b) wherein radiation is listed as a kit component). It is not clear if Applicant intended to recite a radioactive agent. Alternatively, it not apparent how a kit contains "radiation" per se if this was indeed Applicant's intent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 22, 26-28, and 30-34 under 35 U.S.C. 102(b) as being anticipated by the Bayer Product Information Sheet for Suramin, is **withdrawn** in light of Applicants' amendments. Claim 22 has been amended to require the presence of a cytotoxic agent in the claimed kit, in addition to suramin formulated in a pharmaceutical carrier.

Claim Rejections - 35 USC § 103 – New Ground of Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 26-28, 30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Agyin *et al.*** (USP No. 6,900,235; Issued May 31, 2005; Filed Sep. 29, 2000) (newly cited).

Agyin *et al.* disclose benzimidazole compounds for the treatment of cancers (Abstract; col. 2, line 39 to col. 3, line 61). The benzimidazole compounds are inhibitors of microtubules as recited in claim 22 (col. 25, lines 43-67; Table 5). The compounds of the invention are disclosed to be useful in combination therapy, such as by combining the benzimidazole compound with a chemotherapeutic agent and/or "potentiator" (col. 17, lines 1-60; col. 23, lines 29-31). A suitable potentiator is suramin as recited in claim 22 (col. 17, lines 56-57).

Agyin *et al.* disclose pharmaceutical kits for the treatment of cancer comprising one or more containers containing a pharmaceutical composition comprising a compound of the invention, pharmaceutically acceptable carriers, and instructions, *e.g.*, printed instructions either as inserts or as labels, indicating quantities of the components to be administered, guidelines for administration, and/or guidelines for mixing the components (col. 24, lines 7-22).

With regard to claim 26, Agyin *et al.* teach that carboplatin is a chemotherapeutic agent that may be combined with the disclosed anti-microtubule compounds (Table 3A) and that the compounds of the invention can be combined with chemotherapeutic agents **and**/or potentiators to provide combination therapy (col. 23, lines 29-31). Accordingly, addition of both suramin and carboplatin to a kit comprising an anti-microtubule compound as disclosed in Agyin *et al.* would have been obvious to one skilled in the art at the time the invention was made.

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to formulate a kit comprising suramin as a potentiator and an anti-microtubule agent as disclosed in Agyin *et al.* for the treatment of cancer. One skilled in the art would have been motivated to

additionally provide instructions for the therapeutic use of a suramin potentiator in combination with an anti-microtubule agent of Agyin *et al*. As discussed in previous Office Actions, there must be a functional relationship between the printed matter and a substrate in order for printed material to have any patentable weight.

In is noted that *In re Ngai* supports the rejection of pharmaceutical kits that differ from the prior art only in the content of the provided instructions. The following section of the M.P.E.P., as noted by Applicants in their response filed 9/10/2007 (page 7) is deemed relevant to the present claims:

> "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even though the content of the instructions differed.). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983) ("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.")." M.P.E.P. § 2112.01

The decision in *Gulack* held that there must be a functional relationship between the printed matter and a substrate in order for printed material to have any patentable weight. However, in *Ngai*, the court distinguished claims directed to a kit comprising instructions and a buffer (more closely related to the present case) from the printed band and instructions at issue in *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. In *Ngai*, addition of a new set of instructions into a known kit was held to not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. In the present case, the printed matter in no way depends on the kit (*i.e*., a kit containing suramin formulated in a pharmaceutical carrier and a cytotoxic agent), and the kit does not depend on the printed matter (*i.e*., instructions for administering suramin in combination with cytotoxic agents). All that the printed matter does is

teach a method of administering an obvious product. As the court stated in *Ngai*, "If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by *Gulack*. Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product." (Emphasis added).

With regard to claims 27-28 and 32-34, in view of the court decisions in *Gulack* and especially *Ngai*, it is the position of the Examiner that the instantly claimed instructions for using suramin in combination with cytotoxic agents do not provide a functional relationship between the printed matter and a substrate and thus are not given patentable weight. All the printed matter does is teach a new use for an obvious kit comprising suramin and a cytotoxic agent. Further, claim 22 recites that the required dose of suramin **can be** determined in step (b) by the steps (b1) – (b3). However, the claims do not *require* that such steps be carried out, as evidenced by the limitation "can be determined". Accordingly, the Examiner is appropriately interpreting the limitation "can be determined" as an **option**, not a requirement of the claims.

Note that the nomogram recited in claim 30 does provide a functional relationship between the printed matter (instructions) and the claimed kit. However, because claim 22 does not *require* that the nomogram be used to determine the dose of suramin administered, claim 30 is included in this rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
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